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Hon. Esther Salas, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Federal Building and U.S. Courthouse
50 Walnut St.
Newark, NJ 07101

Re: *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*
U.S.D.C., District of New Jersey
Civil Action No.: 2:14-cv-02094-ES-MAH

Dear Judge Salas:

This firm, along with Jones Day, represents Defendant Celgene Corporation in the above-referenced matter. We write in response to Mylan's submission on December 16, 2014 (Dkt. No. 51) regarding Judge Sweet's decision to grant a preliminary injunction in *The People of the State of New York v. Actavis, PLC and Forest Laboratories, LLC* , Civ. Action No. 14-7473 (S.D.N.Y.) ("*Namenda*"). Mylan contends that the *Namenda* opinion "provides critical additional support for, and is directly relevant to Mylan's position" in opposition to Celgene's motion to dismiss. (Dkt. No. 51 at 1.) To the contrary, the *Namenda* case is on completely different factual footing and actually underscores the deficiencies with Mylan's complaint that require dismissal.

As Mylan concedes (Mylan Letter, Dkt. No. 51 at 1), *Namenda* involved a different claim based on product redesign, rather than a claim of a refusal to assist a rival, as Mylan alleges Celgene has done here. Counsel for Mylan conceded at the outset of the oral argument before this Court that a seller acting alone has no general duty to deal with, much less assist, its would-be competitors under Section 2 of the Sherman Act. (Tr. at 6:3-7:20). In the words of Judge Diane Wood:

> [A] complaint . . . which takes the form "X is a monopolist, [and] X didn't help its competitors enter the market so that they could challenge its monopoly . . ." does not state a claim under Section 2. The reason is because the antitrust laws do not impose that kind of affirmative duty . . . .

Goldwasser v. Ameritech Corp., 222 F.3d 390, 400 (7th Cir. 2000). The Supreme Court's recent decisions in *Trinko* and *Linkline* reaffirm that Mylan cannot fall within the narrow "*Aspen*"

exception, requiring both a prior course of dealing and business conduct that is wholly irrational but for its ability to hurt the rival.

1. Sherman Act Section 1

To avoid the strictures of a Section 2 monopolization claim, Mylan asserts that the distribution arrangement Celgene has with its distributors violates Section 1 of the Sherman Act, which proscribes conspiracies in restraint of trade. But Mylan's argument that *Namenda* supports its conspiracy claim (Mylan Letter, Dkt. No. 51 at 2) is unpersuasive, both as to the element of causation and as to the capacity of Celgene's distributors to conspire under Third Circuit law.

First, the distribution agreement Judge Sweet found could violate Section 1 in *Namenda* is very different from the agreements alleged here. Critically, Namenda is not subject to an FDA-mandated (REMS) restricted distribution program. Rather, Actavis decided to restrict distribution of Namenda IR only to patients who had a Medical Necessity Form signed by their doctor as a way to effectuate the switch to Namenda XR and thwart generic competition. (*Namenda* Slip Op. at 64-67.) Actavis's sole distributor agreed with Actavis to restrict distribution in this way even though there was no legal requirement that it do so. (*Id.*) By contrast, Mylan neither alleges nor argues that it qualifies as an authorized purchaser from Celgene's distributors under the FDA-approved REMS program, nor does Mylan dispute that any such sale would subject Celgene to penalties for violating the statute. *See* 21 U.S.C. §§ 352(y) and 333(f)(4); Donald O. Beers & Kurt R. Karst, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* 2-22 (7th ed. 2008). The FDA has given Celgene alone the right to sell directly to generics, and has done so, as the complaint acknowledges, as a matter of "enforcement discretion." (Compl. ¶¶83 & 90-91.)

Indeed, Judge Sweet distinguished the situation in *Namenda* from a case in which "the defendant-monopolist would continue to enjoy monopoly power with or without the agreement in question." (Slip. Op. at 125 (distinguishing *E&L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 30 (2d Cir. 2006)).) Similarly, here, Celgene has the right to sell to Mylan itself (as it has sold to others) when its business concerns are satisfied, and any inability of Mylan to obtain product from Celgene's distributors is a direct consequence of the FDA-approved restriction on the distribution of Thalomid® and Revlimid® under the REMS program.

On the question of the distributors' capacity to conspire under Section 1, moreover, *Namenda* does not support Mylan's claim that the plurality requirement of Section 1 is satisfied whenever a company and its alleged agent are "separate economic actors, occupying different roles in the [drug] supply chain." (Mylan Letter, Dkt No. 51 at 2.) That description applies fully to the sales representatives and other agents held incapable of conspiracy by the Third Circuit in *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125 (3d Cir. 1995) and *Harold Friedman, Inc. v. Kroger Co.*, 581 F.2d 1068 (3d Cir. 1978). In those cases, as here, Section 1 did not apply where the alleged conspirators had neither knowledge of the anticompetitive objective, discretion

to act, nor ability to benefit from any alleged reduction in competition. This is the third opportunity Mylan has had to address the merits of those controlling Third Circuit decisions, and it has failed once again to do so.

2. Relevant Market

Mylan also argues that the *Namenda* decision supports its argument that the relevant market should consist of a single branded drug and its generic equivalents (here, Thalomid® or Revlimid® *each* fit that narrow definition). (Mylan Letter, Dkt. No. 51 at 2.) But the evidence regarding the relevant market in *Namenda* was strikingly different from the conclusory allegations regarding the relevant market in Mylan's complaint. Judge Sweet found that "[c]urrently, the two forms of Namenda produced and sold by Forest, Namenda IR tablets and liquid solution, and Namenda XR capsules, are the only available NMDA receptor antagonists approved to treat Alzheimer's disease." (Slip Op. at 16.)[1] Moreover, at the time it was approved, Namenda IR "was the first and only medication approved for patients with moderate-to-severe Alzheimer's disease." (*Id.* at 30.) And, while there are three other treatments for Alzheimer's on the market (*id.* at 14), all three are acetylcholinesterase inhibitors ("CIs" or "ACIs") and work to "reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells" (*id.* at 15). Namenda, by contrast, is an N-Methyl D-Aspartate ("NMDA") receptor antagonist and "works differently from CIs." (*Id.* at 15.) Whereas "doctors commonly prescribe a CI in the early stage of the disease" (*id.* at 39), "Namenda IR is not indicated for use with mild-stage Alzheimer's Disease patients" (*id.* at 40). As such, Judge Sweet found that "doctors do not consider CIs to be reasonable substitutes for Namenda." (*Id.* at 41.) Rather, "the two classes of drugs are complements: 70% of Namenda patients also take an ACI." (*Id.* at 42.)

Here, by contrast, Mylan's complaint contains no allegations approaching what Judge Sweet found in *Namenda*. There is nothing alleged in the complaint to suggest that Thalomid® or Revlimid® are the only treatments for any disease or condition or are the only drugs that act on a certain physiological mechanism in order to treat a particular disease or condition, as was true of Namenda. Indeed, there is no allegation even addressing why Thalomid® and Revlimid®, both teratogens used to treat patients with multiple myeloma, do not even compete with each other, much less other treatments for cancer. *Cf. Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 573 (S.D.N.Y. 2011) (dismissing complaint for failure to plead facts demonstrating no other drug was an acceptable substitute). In stark contrast to the facts in *Namenda,* Mylan's complaint utterly fails to allege any facts distinguishing Thalomid® and Revlimid® from any other treatments for multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma, or leprosy. This failure is fatal to Mylan's complaint.

[1] Actavis acquired Forest in July 2014. (Slip Op. at 11.)

3. Allegedly Pretextual Reasons

Finally, Mylan argues that *Namenda* is relevant because, in considering the claim that Actavis's product redesign was unlawful under Section 2, the court characterized the business justifications proffered by Actavis to show that its unilateral conduct was not economically irrational as "pretextual." (Dkt. No. 52 at 2-3.) Again, the contrast to *Namenda* is striking. There, the Court found the claimed justifications to be entirely invented, that is, objectively untrue. Indeed, Actavis openly "stated that the very purpose of the limited distribution is to blunt generic competition and prevent the operation of state generic substitution laws." (Slip Op. at 70.) Against this backdrop, the court found that Actavis's post hoc pro-competitive justifications—namely cost savings and greater "focus" (*id.* at 73)—were not plausible (*id.* at 116.) Indeed, neither defendants nor their economic experts had even quantified the purported "savings." (*Id.* at 73.)

In contrast, the concededly real, concededly significant safety and liability concerns that Celgene has raised are both subject to judicial notice and acknowledged by Mylan. They include, among other business concerns, (1) the obvious dangers of thalidomide and lenalidomide, as reflected by the FDA-required REMS safety program, and (2) the products liability exposure to Celgene for the conduct of others that even Mylan agrees requires indemnification. This, then, is not a case like *Namenda*, where the objective reasons to refuse to deal do not exist. It is a case where those reasons admittedly do exist, but Mylan proposes to prove that Celgene was insincere about them. But monopolization under Section 2 is not a thought crime. Even the cases on which Mylan relies agree that Section 2 liability turns upon the "[defendant's alleged] conduct, not upon the intent behind it." *United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir. 2001); *see also, e.g.*, Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 Antitrust L.J. 413, 416-17 (2006) ("[W]hat matters are the objective economic considerations for a reasonable person, and not the state of mind of" the defendant.). Under Mylan's theory, a seller who inflicted exactly the same alleged competitive harm (by refusing sales and "excluding" Mylan), but who truly cared about safety and liability, would be completely free of antitrust liability. Yet another to whom safety was less important would owe trebled damages. The law is otherwise. Where, as here, there are "objective economic considerations" on which "a reasonable person" might refuse to deal, *id.*, there is no duty to deal, even if, in the words of the Supreme Court, the refusal "can bankrupt the plaintiffs." *Linkline*, 455 U.S. at 457.

Indeed, as counsel for Mylan repeatedly conceded at oral argument, the test of Section 2 is *objective*. (Tr. at 45:13-16; 61:8-9.) Accordingly, Celgene's alleged duty to aid its competitor, despite the existence of legitimate reasons not to do so, does not turn on Celgene's subjective intent: "A legitimate purpose renders any accompanying purpose [to disadvantage rivals] irrelevant; regardless of motive, no firm has a general duty to injure itself in order to benefit a rival." IIIA Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 773e, at 255 (3d ed. 2005) (citing *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 368-70 (9th Cir. 1988)); *see* Celgene

Reply (Dkt. No. 31) at 7 (collecting cases). Where, as here, the objectively legitimate reasons for a seller in Celgene's position not to assist a rival are conceded, the inquiry is over.

Finally, while we have shown that the *Namenda* decision does not support the propositions Mylan advances, we do not wish to give the wrong impression. *Namenda*'s conclusions as to the "product-hopping" allegations present in that case represent a dramatic departure from the principles of antitrust law embraced by the Supreme Court in *Trinko*, *Linkline*, and numerous other decisions.[2] We understand that the unprecedented injunction entered in *Namenda* will soon be reviewed (and we believe, remedied) by the Second Circuit. Thus the decision should not be accorded the same deference as *Trinko* and *Linkline*.[3]

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For the foregoing reasons, far from supporting Mylan's claims, the *Namenda* decision underscores the deficiencies with Mylan's allegations here and provides further support for dismissing the complaint.

Respectfully submitted,

NORRIS, MCLAUGHLIN & MARCUS

/S/ DANIEL R. GUADALUPE

JONES DAY

/S/ KEVIN D. MCDONALD

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[2] Moreover, as Mylan points out in its letter, the *Namenda* court was dealing with a "product-hopping" case, not a refusal-to-deal case. Thus, the *Namenda* court applied a balancing test gleaned from *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001), that is simply not applicable to refusals to deal. (Slip Op. at 114-15.)

[3] Indeed, the *Microsoft* balancing test has been criticized by courts and commentators alike. *See, e.g.*, *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010) (rejecting balancing test and noting that "[a]lthough one federal court of appeals [*Microsoft*] has nominally included a balancing component in its test, it has not yet attempted to apply it"); Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 Berkeley Tech. L.J. 1, 52 (2012) ("[The DC Circuit's balancing] test is also opaque, and its only saving grace, thus far, is that the court has had no occasion to apply it.").